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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,653	02/02/1999	HERMANN WAGNER	C1041/7002-H	8996

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HELEN C LOCKHART
C/O WOLF GREENFIELD & SACKS PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 022102211

EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	26

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/241,653	WAGNER ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-41 and 51-74* is/are allowed.

6)☒ Claim(s) *42-50 and 75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

File

DETAILED ACTION

This Office action is in response to the communication filed May 13, 2002, Paper No. 25. Claims 1-77 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement filed July 5, 2001 fails to comply with 37 CFR 1.98(a)(2)(iii), which requires a legible copy of each cited U.S. application specification including the claims, or foreign patent, or that portion which caused it to be listed including any claims directed to that portion; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The IDS has been placed in the application file, but the information referred to therein has not been considered.

The list of pending patent applications listed on the modified 1449 form filed July 5, 2001, Paper No. 20, has been entered, but the listed applications have not been considered because copies of the speicifications and claims have not been provided as required under 37 CFR 1.98(a)(2).

Response to Arguments

Withdrawn Rejections

Rejection of claims 1-12 and 14-77 under 35 U.S.C. 102(e) as being anticipated by Krieg et al is withdrawn in light of Applicant's arguments filed May 13, 2002, Paper No. 25, and in light of the declaration filed July 5, 2001, Paper No. 21.

Rejection of claims 1-77 under 35 U.S.C. 103(a) as being unpatentable over Krieg et al (USPN 6,214,806) in view of Krieg et al (USPN 6,207,646) is withdrawn in light of Applicant's arguments filed May 13, 2002, Paper No. 25, and in light of the declaration filed July 5, 2001, Paper No. 21.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-50 and 75-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating a subject at risk of developing thrombocytopenia comprising diminishing platelet count decreases, or treating anemia, comprising administration of CpG containing oligonucleotides, does not reasonably provide enablement for preventing platelet count decreases or preventing anemia in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of treating a subject at risk of developing thrombocytopenia comprising the administration of a CpG oligonucleotide in an amount effective to prevent any decrease in platelet counts in any subject. The claims are also drawn to

methods of preventing anemia comprising the administration of a CpG oligonucleotide of at least 8 nucleotides in an amount effective to induce erythropoiesis.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward a method of treating a subject at risk of developing thrombocytopenia comprising administration of a CpG containing oligonucleotide of at least 8 nucleotides and further whereby any decrease in platelet counts is prevented. Applicants have not provided guidance in the specification toward a method of preventing anemia in a subject comprising the administration of a CpG containing oligonucleotide of at least 8 nucleotides.

The specification teaches enhanced immune system recovery in sublethally irradiated mice (i.e. a mitigation of myelosuppression) comprising the administration of CpG containing oligonucleotides, whereby increased numbers of splenic GM-CFU, increased antigen specific CTL responses and enhanced resistance to Listeria monocytogenes infections are obtained following administration of CpG containing oligonucleotides. The specification also teaches an increase in platelet cells, or a diminution of platelet cell decreases in 5-FU treated mice following administration of CpG containing oligonucleotides. The specification fails to teach the prevention of anemia in any and/or all subjects or the complete prevention of decreases in platelet cell counts in subjects at risk of thrombocytopenia. One skilled in the art would not

accept on its face the examples given in the specification of increased numbers of splenic GM-CFU, increased antigen specific CTL responses and enhanced resistance to Listeria monocytogenes infections following administration of CpG containing oligonucleotides, or the diminution of platelet cell decreases in 5-FU treated mice following administration of CpG containing oligonucleotides, as being correlative or representative of the ability to prevent anemia or the ability to prevent any decrease in platelet counts in subjects at risk of developing thrombocytopenia in view of the lack of guidance in the specification and known unpredictability associated with the ability to provide such broad preventive measures comprising the administration of CpG containing oligonucleotides in any subject. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with preventing anemia or preventing platelet cell decreases in any subject.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to methods of treating any subject at risk of developing thrombocytopenia comprising the administration of a CpG oligonucleotide in an amount effective to prevent any decrease in platelet counts in that subject. The claims are also drawn to methods of preventing anemia comprising the administration of a CpG oligonucleotide of at least 8 nucleotides in an amount effective to induce erythropoiesis. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the ability to prevent anemia in a subject or the ability to prevent any decreases in platelet counts

in a subject comprising the administration of a CpG containing oligonucleotide. Since the specification fails to provide any particular guidance for such broad prevention, and since determination of the factors required for achieving prevention of anemia or prevention of any decrease in platelets in a subject is highly unpredictable, it would require undue experimentation to practice the invention over the broad scope claimed.

Allowable Subject Matter

Claims 1-41, 51-74 are free of the prior art searched.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SEAN McGARRY
PRIMARY EXAMINER

JZ

July 24, 2002